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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/852,850 05/11/2001 Kohshi Ueno 0425-0838P 7071

2292 7590 08/07/2002

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EXAMINER

PATEL, SUDHAKER B

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 08/07/2002

4

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/852,850

Applicant(s)

Koshi Ueno et al

Examiner

Sudhakar Patel

Art Unit

1624



— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on May 24, 2002
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 4, and 6-12 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4, 6, 7, 10, and 12 is/are rejected.
- 7) ☒ Claim(s) 8, 9, and 11 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirements.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/509,778.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other: _____

Art Unit: 1624

DETAILED ACTION

Applicants' communication paper #3 dated 5/24/02 is acknowledged. The claims in this applications are the claims 1,2,4,6-12.

(I). Restriction/Election: Applicants desired clarification for the restriction/election.

As applicants are aware, the parent U. S. Application Sr. No. 09509778 filed 3/31/2000 , allowed U.S.P. 6340759, was restricted in the following way:

Group I, claim(s) 1-13 (in part), drawn to compounds, composition, and a method of use of Formula (I) wherein A = Phenyl; B = Aryl (i.e. Non-heterocycle)..

Group II, claim(s) 1-13 (in part), drawn to compounds, composition, and a method of use of Formula (I) wherein A = Pyridine; B = Non-Heterocycle, and Heterocycle only involving imidazole, piperidine, furan, thiene , pyran. And ben-fused structures..

Group III, claim(s) 1-13(in part), drawn to compounds, composition, and a method of use of Formula (I) wherein A = Thiophene, furan; B = Heterocycle having 6-membered ring e.g. morpholine, 1,4; 1,3; diazine/diazine etc..

Group IV, claim(s) 1-13 (in part), drawn to compounds, composition, and a method of use of Formula (I) wherein A = Heterocycle or Non-Heterocycle; B = Heterocycle with 7-members and larger.

Group V, claim(s) 1-13 (in part), drawn to compounds not included in above groups.

Invention of Group III was examined for the parent application Sr. No.09509778.

Art Unit: 1624

For the instant application Sr. No. 09852850 filed 5/11/2001, applicants have elected invention of Group I with Formula (I) wherein A = Phenyl; B = Aryl (i.e. Non-heterocycle), thus providing isoquinoline core. Therefore, inventions of Groups II, IV, V remain as non-elected inventions.

The election/restriction is deemed proper and is made **FINAL**.

(II). Rejections withdrawal:

- ◆ Applicants amendments to claims 1,2,4,6,7,8,9-12, cancellation of term “preventing” together with their remarks and arguments are sufficient for the withdrawal of rejections A).-E). made under 35 U.S.C. 112 paragraph second.
- ◆ Applicants amendments to claims 1,2,4,6,7,8,9-12, cancellation of term “preventing” together with their remarks and arguments are sufficient for the withdrawal of rejections made under 35 U.S.C. 112 paragraph one.

(III). New rejections:

Upon further review and considerations the application is not found to be ready for allowance for following art rejections:

(IIIA). *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1624

Claims 1,4,6,12 are rejected under 35 U.S.C. 112, second para. as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regards as the invention.

- ▶ Claim 4 recites the limitation "R. = H; R. = N-substituted 1,4-diazine" in claim 1, but recites the compounds as: "pharmacologically acceptable salts" instead of "pharmaceutically acceptable salt". There is insufficient antecedent basis for this limitation in the claim.
- ▶ Claim 4 recites variables R31 = R1; R32 = R. and R33 = B. However claims 6 and 12 recite compounds with R33 = 2-hydroxy ethoxy phenyl(see compound # 3 on page 14 of amendment paper # 3 dated 5/24/02). It is very confusing to read the definitions of B in claim 1 on page 3 line 12 as:" optionally substituted aryl" or in line 15 "a lower alkoxy aryloxy group" or in the figures on pages 3,4 where applicable variables Q, R7-R13, and integers z,m,p when computed give the same derivative. It is exactly not very clear as to what applicants want to present with the said duplicated citation in the claim 1. Clarification is requested.

(IIB).

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

Art Unit: 1624

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

- Claims 1,2,4,7 are rejected under 35 U.S.C. 102(b) as being anticipated by Cho et al (Chem. Abstr. 127:190707; also cited as Arch. Pharm. Res.J.,20/3,264-268(1997). In the instant claims, the compounds arrived at by computing various values for the variables as:

R1 = H; R. = Substituted 1,4-diazine with R4 = Alkyl; n = 0; B = Optionally substituted aryl; R. = H, provide compound(s) which are listed under CAS RN # 194292-31-4(= Isoquinoline,1-(4-methyl-1-piperazinyl)3-phenyl-,monohydrochloride); CAS RN # 194292-32-5(= Isoquinoline, 3-(4-bromophenyl)-1-(4-methyl-1-piperazinyl)-monohydrochloride). Thus, instantly claimed compounds read on the compounds of the reference.

- Claims 1,2,4,7 are rejected under 35 U.S.C. 102(b) as being anticipated by Behrens, Carl H. (Chem. Abstr. 113:211863; also cited as U.S.P. 4942163). In the instant claims the compounds arrived at by computing various values for the variables as:

R1 = alkyl; R. = Substituted 1,4-diazine with R4 = Alkyl or R. = -N(R5)(R6) wherein R5 = H or lower alkyl, R6 = diloweralkyl aminoalkyl = -CH₂-CH₂-N(Me)₂; n = 0; B = Optionally substituted aryl; R. = H, provide disclosed compound which are listed under CAS RN # 130370-12-6 (= Isoquinoline, 7-methyl-1-(4-methyl-1-piperazinyl)-3-(1-naphthalenyl)-; CAS RN # 130370-14-8(= 1,2-Ethanediamine, N,N,N'-trimethyl-N'-(7-

Art Unit: 1624

methyl-3-)1-naphthalenyl)-1-isoquinoliny)-. Thus, instantly claimed compounds read on the compounds of the reference.

- Claims 1,2,4,7 are rejected under 35 U.S.C. 102(b) as being anticipated by Lerch et al (Chem. Abstr.82:16836 ; also cited as DE 2314985). In the instant claims the compounds arrived at by computing various values for the variables as:

R1 = H; R. = imidazole; n = 0; B = Optionally substituted aryl; R. = H or halogen, provide compound(s) which are listed in ref. '985 and embraced by Formula I and are disclosed under CAS RN # 55150-98-6(= Isoquinoline, 4-chloro-1-(1H-imidazol-1-yl)-3-phenyl); CAS RN # 55151-08-1(= Isoquinoline,1-(1H-imidazol-1-yl)-3-phenyl-,ethandioate). Thus, instantly claimed compounds read on the compounds of the reference.

(IIC).

Claim Rejections - 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1624

Claims 1,2,4,7,10, are rejected under 35 U.S.C. 103(a) as being unpatentable over Simmonds et al(GB 1545767). In the instant claims the compounds arrived at by computing various values for the variables as:

R1 = H; R. = -N(R5)(R6) wherein R5 and R6 = lower Alkyl; n = 0; B = Optionally substituted aryl; R. = lower alkyl, provide disclosed compound which are disclosed by the ref.'767 and listed (See Formula I of abstract and claim 1, and compounds encompassed) by CAS RN # 72240-39-2(=1-isoquinolineamine, N,N,3-trimethyl-4-phenyl).

The reference '767 teaches the making of substituted 1-amino-Isoquinoline derivatives and their activity as antiinflammatory esp. Antirheumatic and or activity related to central nervous system.

The instant claims differ by having the substituents at different positions than the reference compounds e.g. in the claims B can be phenyl and R3 can be Me.

While applicants claim novel compounds having pharmaceutical use, their attention is drawn to the fact that compounds having the same radicals at different positions on the nucleus are position isomers. Position isomerism involves close structural similarity and are expected to possess similar chemical and physical properties. Thus, the disclosure of the compound itself renders prima facie obvious over its isomers. Isomer is expected to be preparable by the same method and to have the same properties. This expectation is then deemed the motivation for preparing isomers and isomeric compounds as claimed herein. which The claimed compounds are isomer(s) of the reference compound and are unpatentable over the prior art unless the same

Art Unit: 1624

possess some unobvious or unexpected beneficial property not possessed by the prior art. In re Jones (CCPA 1947) 102 F2d 638, 74 USPQ 152. In re Norris (CCPA 1950) 179 F2d 970, 84 USPQ 458.

One of ordinary skill in the art would have been motivated to make the claimed compounds by exchanging the positions of the methyl, phenyl. And other groups of the ref. '767 since such compounds would have been suggested by the reference as a whole. The requisite motivation stems from the expectation that compounds so structurally similar would be expected to possess pharmaceutical properties (in re Wood, 199 USPQ 137).

(IV).

Allowable Subject Matter

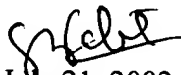
Claims 8,9,11 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sudhaker Patel whose telephone number is (703) 308 4709.

The examiner can normally be reached on Monday thru' Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by the phone are unsuccessful, the examiner's supervisor, Dr. Mukund Shah can be reached at (703) 308 4716 or Sr. Patent Examiner Mr. Richard Raymond at (703) 308 4523.

A facsimile center has been established for Group 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machine are (703) 308-4556 or (703) 305-3592.

Any inquiry of general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308 1235.


Sp July 21, 2002.


Mukund J. Shah
SUPERVISOR
PENDING
7/21/02